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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,636	SERTEYN ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *15,17-24,26-32,34-37,39 and 40* is/are pending in the application.

5a) Of the above claim(s) *24 and 27-31* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *15,17-23,26,32,34-37,39 and 40* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed November 3, 2011 is acknowledged and has been entered. Claims 15 and 26 have been amended. Claims 24 and 27-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 15, 17-24, 26-32, 34-37, 39, and 40 are pending. Claims 15, 17-23, 26, 32, 34-37, 39, and 40 are under examination.

Amendment Entry

2. Any rejections or objections not reiterated herein, have been withdrawn.

3. In light of Applicant's amendment and arguments, the rejection of claims 15, 17-21, 26, 32, 34, 36, 37, and 39 under 35 U.S.C. 102(b) as being anticipated by Uchida et al. (US Patent 5,552,292), is hereby, withdrawn.

4. In light of Applicant's amendment and arguments, the rejections of claims 22, 23, 35, and 40 under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) in view of each one of Deby et al. (US Patent 5,460,961); Deby-Dupont et al. (Veterinary Immunology and Immunopathology 66: 257-271 (1998)); and Wilson et al. (US 2006/0257879), are hereby, withdrawn.

New Grounds of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 15, 17-23, 26, 32, 34-37, 39, and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. ASN 12/669,781. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a method and kit for performing SIEFED and ELISA to determine activation status of a cell by detecting and measuring the cell enzyme including those released from the cell and specific enzyme activity of active isoform of the enzyme comprising antibodies that bind to the enzyme, solid phase substrate, and label reagents to detect and measure total enzyme concentration and specific enzyme activity thereof whereupon the enzyme is initially immunocaptured into the solid phase then washed to remove interfering components prior to detection and measurement of the active enzyme using a specific substrate that is transformed by the active enzyme into a detectable fluorometric reaction product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 15, 17, 19-21, 26, 32, 34, 36, 37, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) in view of Janckila et al. (Tartrate-resistant Acid Phosphatase Isoform 5b as Serum Marker of Osteoplastic Activity, Clinical Chemistry 47 (1): 74-80 (2001)).

Uchida et al. disclose a kit comprising antibodies effective for immunocapturing enzyme released by neutrophils in a biological sample such as myeloperoxidase (MPO) and elastase (col. 2, lines 10-41, 61-64; col. 5, lines 36-41; Example 2). The kit further comprises a chromogenic substrate effective for detecting and measuring activity of an enzyme (Example 1).

Uchida et al. disclose a method for detecting and measuring neutrophil enzymes in a biological sample which may be released from the neutrophils so as to provide indication of disease or pathology (inflammatory gastrointestinal disorder, colon cancer). The neutrophil enzymes include myeloperoxidase (MPO) and elastase (Abstract; col. 2, lines 10-41). The enzyme granules released may be found in serum, saliva, breast

milk, and faecal derived samples (col. 2, lines 61-64). Uchida et al. specifically teach using enzyme-linked immunosorbent assay (ELISA) method and reagents to detect and/or measure the amount of the enzyme released by the neutrophil cells. Uchida et al. teach that the amount of released enzyme content provides indication of the activation of neutrophil cells (col. 3, line 61 to col. 4, line 25; col. 7, lines 15-18; Example 3). Uchida et al. teach comparing the amount of released enzyme to a reference value from subjects without disease (col. 4, lines 26-62; col. 5, lines 5-7; Table 2; Example 2)

Uchida et al. differ from the instant invention in failing to teach detecting and/or measuring the enzymatic activity of the immunocaptured enzyme.

Janckila et al. performed immunological assays that detect and measure total enzyme protein concentration and enzyme specific activity simultaneously in duplicate microwells. Janckila et al. teach using anti-enzyme monoclonal antibody coated onto the microwells to immunocapture the target enzyme for enzyme-linked immunosorbent assay of the total enzyme, and then specific immunological extraction followed by enzymatic detection and measure of the enzymatic activity. Janckila et al. teach performing a washing step after immunocapture to remove any components that may interfere with the measurement of enzyme activity (p. 75, cols. 1). Janckila et al. teach differentially measuring both total enzyme protein and active isoform enzyme activity using the same monoclonal antibody (p. 75, col. 2). Janckila et al. compare and correlate measured total enzyme protein and active isoform enzyme activity between healthy subjects without disease and pathologic subject manifesting disease resulting from the presence and activity of the enzyme (p. 75, col. 2 to p. 76, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Janckila into the method and kit for detecting and measuring neutrophil enzyme and activity of Uchida because Janckila specifically taught that total and specific isoforms of active enzymes can be detected and measured both for concentration and differential specific activity so as to provide activation status of cells that release them; thus, providing improved specificity and sensitivity of enzyme assays.

7. Claims 15, 17, 19-21, 26, 32, 36, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deby et al. (US Patent 5,460,961) in view of Janckila et al. (Clinical Chemistry 47 (1): 74-80 (2001)).

Deby et al. disclose a kit comprising antibodies effective for immunocapturing enzyme released by neutrophils such as myeloperoxidase (MPO) in a biological sample. The kit further comprises a chromogenic substrate effective for detecting and measuring activity of an enzyme (col. 21, line 36 to col. 22, line 6).

Deby et al. disclose a method for detecting and measuring a neutrophil enzyme, i.e. recombinant myeloperoxidase (MPO) in a sample. Deby et al. specifically teach using ELISA kit reagents and method to detect and/or measure the amount of the enzyme released by the neutrophil cells. Deby et al. teach that an effective amount of nitrite in the form of sodium salt or any other form of earth alkali salt can be added into the reaction medium so as to enable generation of enhanced signal during

measurement. Deby et al. teach that the amount of released enzyme content provides indication of the activation of the neutrophil cells (col. 21, line 36 to col. 22, line 6).

Deby et al. differ from the instant invention in failing to teach detecting and/or measuring the enzymatic activity of the immunocaptured enzyme.

Janckila et al. is discussed supra.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Janckila into the method and kit for detecting and measuring neutrophil enzyme and activity of Deby because Janckila specifically taught that total and specific isoforms of active enzymes can be detected and measured both for concentration and differential specific activity so as to provide activation status of cells that release them; thus, providing improved specificity and sensitivity of enzyme assays.

8. Claim 18, 23, and 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) or Deby et al. (US Patent 5,460,961) in view of Janckila et al. (Clinical Chemistry 47 (1): 74-80 (2001)) as applied to claims 15, 17, 19-21, 26, 32, 34, 36, 37, 39, and 40 above, and further in view of Wilson et al. (US 2006/0257879).

Uchida et al., Deby et al. and Janckila et al. are discussed supra. Uchida et al., Deby et al., and Janckila et al. differ from the instant invention in failing to teach using a fluorometric substrate.

Wilson et al. teach that peroxidase activity is present in many cells and that many fluorogenic substrates for horseradish peroxidase are well known in the art and are commercially available in ELISA kits. Wilson et al. specifically teach that 10-acetyl-3,7-dihydroxyphenoxazine is a well-known fluorogenic substrate which is advantageous for its ability to react with hydrogen peroxide in the presence of horseradish peroxidase and produce highly fluorescent resolution signal.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate 10-acetyl-3,7-dihydroxyphenoxazine as a fluorogenic substrate into the method of Uchida or Deby as modified by Janckila in immunologically capturing, detecting, and measuring level and activity of MPO enzyme because 10-acetyl-3,7-dihydroxyphenoxazine appears to be an obvious variation of fluorogenic substrates known and used in immunological enzyme assay methods such as those taught by Uchida or Deby or Janckila, which is advantageous for its ability to produce highly fluorescent resolution signal.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) or Deby et al. (US Patent 5,460,961) in view of Janckila et al. (Clinical Chemistry 47 (1): 74-80 (2001)) as applied to claims 15, 17, 19-21, 26, 32, 34, 36, 37, 39, and 40 above, and further in view of Deby-Dupont et al. (Equine Neutrophil Myeloperoxidase in Plasma: design of a radio-immunoassay and first results in septic pathologies, Veterinary Immunology and Immunopathology 66: 257-271 (1998)).

Uchida et al., Deby et al. and Janckila et al. are discussed supra. Uchida et al., Deby et al., and Janckila et al. differ from the instant invention in failing to teach that the mammal is a horse.

Deby-Dupont et al. teach obtaining specific antiserum against MPO and immunologically assaying for the presence and amount of MPO in horses and determining pathological conditions such as strangulation intestinal pathologies which are accompanied by local activation of neutrophils. Such conditions can be revealed by measuring tissular enzymatic activity of the granulocytic enzyme: MPO using the specific antibody (antiserum) to MPO (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to immunologically assay for the amount and activity of enzyme MPO as taught by Uchida or Deby as modified by Janckila, in a blood sample obtained from a horse as taught by Deby-Dupont because Uchida and Deby specifically taught polyclonal and monoclonal antibodies that can be used to capture and extract MPO enzymes using the method taught by Janckila to detect and measure content and activity of MPO from neutrophils, and Deby-Dupont expressly showed the significance of specifically measuring accurate level and activity of MPO in determining conditions such as strangulation intestinal pathologies in horses which occurs by local activation of granulocytes, i.e. neutrophils.

Response to Arguments

10. Applicant's arguments filed November 3, 2011 have been fully considered and are persuasive, but are moot in view of the new grounds of rejection.

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/

Primary Examiner, Art Unit 1641

January 23, 2012